UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-358-JL
Opinion No. 2010 DNH 112

Mutual Pharmaceutical Company, Inc.

OPINION & ORDER

The question in this case is whether a manufacturer may be held liable for injuries caused by a prescription drug. Plaintiff Karen Bartlett, who took the generic drug Sulindac and suffered severe side effects, brought suit against the drug's manufacturer, Mutual Pharmaceutical Company, asserting state-law claims of strict products liability, negligence, and fraud. She alleges, in particular, that Sulindac is an unreasonably dangerous product and that Mutual should have strengthened the drug's safety warning in light of information reported in the medical literature. This court has jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity), because Bartlett is a New Hampshire citizen and Mutual is located in Pennsylvania. Earlier in the case, this court denied Mutual's motion for judgment on the pleadings, see Fed. R. Civ. P. 12(c), rejecting the argument that Bartlett's claims were pre-empted by federal law. See Bartlett v. Mut. Pharm. Co., 659 F. Supp. 2d 279 (D.N.H. 2009).

Both parties have now moved for summary judgment. See Fed. R. Civ. P. 56. After hearing oral argument, this court grants each motion in part. To the extent that Bartlett's claims are based on Mutual's alleged failure to warn of safety risks, Mutual is entitled to summary judgment because Bartlett cannot prove that conduct caused her injuries. Her doctor, who is the person Mutual had a duty to warn, prescribed Sulindac without reading or relying upon its warning label. Thus, no matter what the label said, it would not have affected the doctor's decision to prescribe the drug or otherwise prevented Bartlett's injuries. But to the extent that her claims are based not on the alleged failure to warn, but on the theory that Sulindac is an unreasonably dangerous product, they present a genuine dispute of material fact that must be resolved at trial. Finally, Bartlett is entitled to summary judgment on some of Mutual's affirmative defenses.

I. Applicable legal standard

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). An issue is "genuine" if it could reasonably be resolved in either party's favor at trial, and

"material" if it could sway the outcome under applicable law. Mulvihill v. Top-Flite Golf Co., 335 F.3d 15, 19 (1st Cir. 2003). In making this determination, the "court must scrutinize the record in the light most flattering to the party opposing the motion, indulging all reasonable inferences in that party's favor." Id. On cross-motions for summary judgment, this standard is applied to each party's motion separately. See, e.g., Am. Home Assurance Co. v. AGM Marine Contractors, Inc., 467 F.3d 810, 812 (1st Cir. 2006).

II. Background[1]

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor, Tahsin Ergin, prescribed a non-steroidal anti-inflammatory drug ("NSAID") called Clinoril. Bartlett took the prescription to a pharmacy in Plaistow, New Hampshire, which filled it with Sulindac, a generic version of the drug, manufactured by Mutual. Within weeks, she went to a local emergency room complaining of skin blisters, a fever, eye irritation, and other symptoms. She was soon diagnosed with Stevens-Johnson syndrome ("SJS") progressing to toxic epidermal

[1]This summary is based on undisputed facts in the record. To the extent that the summary judgment motions implicate disputed facts, this court will discuss them in the appropriate part of the analysis, drawing the required inferences in favor of the non-moving party.

necrolysis ("TEN"), a serious and potentially fatal condition characterized by necrosis of the skin and mucous membranes. See Dorland's Illustrated Medical Dictionary 1872 (31st ed. 2007). She spent about three months in the hospital recovering, two of them in a medically induced coma, and emerged with permanent injuries, including blindness.

More than a year before these events, an international medical journal published a study of the link between NSAIDs and SJS/TEN. The study revealed that, from 1980 to 1997, Sulindac had 89 reported cases of SJS/TEN in the Food and Drug Administration's ("FDA") adverse event reporting system, more than any other NSAID on the market and all but four drugs of any kind. See Maja Mockenhaupt et al., The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective, 30 Journal of Rheumatology 2234-2240 (Oct. 2003). Mutual was not aware of that study, however, because it had not been monitoring the medical literature for information about Sulindac's safety risks. Mutual believed that the manufacturer of Clinoril, the brand-name version of the drug, was responsible for such monitoring.

At the time of Bartlett's prescription, Mutual's generic version of Sulindac had the same FDA-approved package insert, or warning label, as Clinoril. The label expressly listed SJS/TEN as potential adverse reactions in its "Adverse Reactions"

section. In its "Warnings" section, however, the label did not mention SJS/TEN by name. Rather, it stated as follows:

> **Hypersensitivity**
>
> Rarely, fever and other evidence of hypersensitivity (see ADVERSE REACTIONS) including abnormalities in one or more liver function tests and severe skin reactions have occurred during therapy with sulindac. Fatalities have occurred in these patients. Hepatitis, jaundice, or both, with or without fever, may occur within the first one to three months of therapy. Determination of liver function should be considered whenever a patient on therapy with sulindac develops unexplained fever, rash or other dermatologic reactions or constitutional symptoms. If unexplained fever or other evidence of hypersensitivity occurs, therapy with sulindac should be discontinued.[2]

Dr. Ergin admitted at his deposition that he never reviewed Mutual's Sulindac label before treating Bartlett and that "nothing about it influenced [his] prescribing of the drug" or what he told Bartlett about it. When asked if he reviewed the identical Clinoril label before treating Bartlett, Dr. Ergin responded "not in detail, no." He then admitted that he never read the part of the Clinoril label that listed SJS/TEN as potential adverse reactions, nor the part that warned of "hypersensitivity" and "severe skin reactions" that have caused fatalities.

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[2]As discussed in Part III, infra, the parties disagree over whether this paragraph, together with the cross-referenced list of adverse reactions, amounted to an adequate warning of SJS/TEN.

Even without reading the warning label, Dr. Ergin knew from his medical background that Sulindac and other NSAIDs carried some risk of causing SJS/TEN. But it was not his usual practice to discuss that risk with patients, and he did not do so with Bartlett. If, however, there had been "strong warnings in place" about "what may well be [a] higher risk of severe reactions like SJS and TEN with Sulindac," Dr. Ergin claims that he likely would have prescribed a different drug for Bartlett that carried less risk of SJS/TEN. He admitted, however, that he still prescribes Sulindac on rare occasions, even after learning of Bartlett's ordeal.

Bartlett brought this suit against Mutual in New Hampshire superior court in January 2008, asserting state-law claims of strict products liability based on failure to warn of safety risks (Count 1), strict products liability based on defective design (Count 2), fraud (Count 3), and negligence based on both failure to warn and defective design (Count 6).[3] She alleges, in particular, that Sulindac's safety risks outweigh its medical benefits, making it an unreasonably dangerous product. She also

[3]Bartlett also asserted a gross negligence claim (Count 7). But "New Hampshire law does not distinguish causes of action based on ordinary and gross negligence," Barnes v. N.H. Karting Ass'n, 128 N.H. 102, 108 (1986), so this court will not separately discuss the gross negligence claim. Bartlett voluntarily dismissed her other claims, for breach of warranty (Counts 4 and 5).

alleges that Mutual should have strengthened Sulindac's safety warning in light of the study mentioned above and other reports in the medical literature about the connection between Sulindac and SJS/TEN.

After removing the case to this court, Mutual moved for judgment on the pleadings, arguing that all of Bartlett's claims were pre-empted by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations issued thereunder. Specifically, Mutual argued that federal law prohibits a manufacturer from unilaterally strengthening the safety warning for a generic drug approved by the FDA, because the warning must remain identical to that of the brand-name drug. This court denied the motion, concluding that federal law allows such changes and thus does not pre-empt Bartlett's claims. See Bartlett, 659 F. Supp. 2d at 279; accord Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010); Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009), petition for cert. filed, 78 U.S.L.W. 3522 (U.S. Feb. 19, 2010) (No. 09-993).

As the case proceeded, the parties engaged in a series of discovery disputes. See, e.g., Bartlett v. Mut. Pharm. Co., 2009 DNH 166 (imposing sanctions against Mutual for the late production of certain FDA filings). With discovery now complete and trial scheduled for August 2010, Mutual has moved for summary judgment on all claims. See Fed. R. Civ. P. 56(b). Bartlett, in

turn, has moved for partial summary judgment on various issues, some of which overlap with those raised by Mutual. See Fed. R. Civ. P. 56(a). This court will address each issue in turn, beginning with the key issues on which both parties seek summary judgment (i.e., the adequacy of Sulindac's safety warning and whether its alleged inadequacy caused Bartlett's injuries) and then turning to the other issues that they have raised separately.

III. Adequacy of the safety warning

The first issue, on which both parties seek summary judgment, is whether Mutual's Sulindac label adequately warned doctors of the risk of SJS/TEN. Bartlett has the burden of proving its inadequacy as an essential element of her claims for strict liability (Count 1) and negligence (Count 6) based on failure to warn. See, e.g., Brochu v. Ortho Pharm. Corp., 642 F.2d 652 (1st Cir. 1981) (applying New Hampshire law); see also Nelson v. Dalkon Shield Claimants Trust, No. 84-276-SD, 1994 WL 255392 (D.N.H. June 8, 1994). "An adequate warning is one reasonable under the circumstances" to notify the doctor of the drug's safety risks. Brochu, 642 F.2d at 657. The adequacy of a given warning must be judged in the light of the facts known at the time, without the benefit of hindsight. Id. "A warning may

be inadequate in factual content, in expression of the facts, or in the method by which it is conveyed." Id.

Bartlett argues that the Sulindac label was inadequate as a matter of law because it failed to mention SJS/TEN in its "Warnings" section, failed to list the severe complications that SJS/TEN can cause (e.g., blindness, coma), and failed to identify the steps that should be taken if they occur, as required by FDA regulations. See 21 C.F.R. § 201.57(e) (2004).[4] Mutual, in contrast, argues that the label was adequate as a matter of law because it expressly listed SJS/TEN in its "Adverse Reactions" section and then cross-referenced them in its "Warnings" section, where it discussed the risk of "hypersensitivity" and "severe skin reactions" that have caused fatalities, as well as the steps that should be taken if "evidence of hypersensitivity occurs." Both parties have proffered expert testimony in support of their respective positions.

While neither party is entitled to summary judgment on this genuinely disputed issue, Mutual is much closer to meeting the summary judgment standard than Bartlett. In Guevara v. Dorsey

[4]Mutual argues that this FDA regulation applies only to manufacturers of brand-name drugs, not generic versions. But this court already rejected that argument in its earlier pre-emption ruling. See Bartlett, 659 F. Supp. 2d at 289 n.13, 298 n.25. In any event, the regulation is not dispositive of the label's adequacy. See Part VIII, infra (explaining that violation of FDA safety regulations is evidence of negligence, but not negligence per se).

Labs., 845 F.2d 364 (1st Cir. 1988), the court of appeals reversed a jury's finding that a drug label was inadequate where the label warned of "hypersensitivity" but "did not specifically warn of the kind of [skin] reaction" the plaintiff suffered, which caused blisters and scarring. Id. at 366. The court reasoned that "the warning, read as a whole, clearly tells doctors" of the risk of such a reaction because, according to the plaintiff's own expert, "a doctor warned about hypersensitivity should know that it could be manifested as a skin rash." Id. at 366-68. The court therefore ruled as a matter of law that a more "detailed admonition" was not required. Id. at 366.

Of course, SJS/TEN is far more serious than a skin rash. It has an estimated mortality rate of 30 to 60 percent and, for those who survive, can cause a range of severe and lifelong health problems, as it has for Bartlett. Nevertheless, some courts have applied reasoning similar to Guevara's in SJS/TEN cases, deeming a drug's safety warning, phrased similarly to the one in this case, adequate as a matter of law. See Ames v. Apothecon, Inc., 431 F. Supp. 2d 566, 573 (D. Md. 2006) ("One might prefer to have SJS/TEN listed in the Warnings section, but the present structure cannot be said to be unreasonable merely because it requires the reader to make a cross-reference."); see also Hall v. Merck, Sharp & Dohme, 774 F. Supp. 604, 606-08 (D. Kan. 1991); Williams v. Ciba-Geigy Corp., 686 F. Supp. 573, 578-

80 (W.D. La. 1988); Serna v. Roche Labs., 684 P.2d 1187, 1188-1190 (N.M. Ct. App. 1984).

This court is not persuaded, however, that summary judgment is appropriate on the current record. Even assuming arguendo that a reasonable doctor would have understood Sulindac's warning of "hypersensitivity" and "severe skin reactions" as a cross-reference to SJS/TEN, the question remains whether the warning should have been clearer, more prominent, and more detailed. Given the severity of SJS/TEN and the study indicating that Sulindac had more reported cases than any other NSAID and all but four other drugs, that question cannot be taken away from the jury. See Brochu, 642 F.2d at at 658-59 (affirming jury's finding that drug label was inadequate where it did not refer to key study indicating higher risk of a severe reaction); see also Marchant v. Dayton Tire & Rubber Co., 836 F.2d 695, 701 (1st Cir. 1988) ("questions regarding the adequacy of warnings are almost always an issue to be resolved by a jury") (quotation omitted). Accordingly, this court denies the parties' cross-motions for summary judgment on this issue.

IV. Causation

The second issue on which both parties seek summary judgment is whether Mutual's alleged failure to issue a stronger warning caused Bartlett's injuries. Bartlett has the burden of proving

causation as an essential element of her claims for strict liability (Count 1) and negligence (Count 6) based on failure to warn. See, e.g., LeFavor v. Ford, 135 N.H. 311, 313 (1992); Brochu, 642 F.2d at 659; Nelson, 1994 WL 255392, at *8. Causation has two components under New Hampshire law: cause-in-fact and legal cause. Carignan v. N.H. Int'l Speedway, Inc., 151 N.H. 409, 414 (2004). "Cause-in-fact requires the plaintiff to show that the injury would not have occurred but for the negligent conduct." Id. Legal cause, in turn, "requires the plaintiff to establish that the negligent conduct was a substantial factor in bringing about the harm." Id. In this context, that means Bartlett "must prove that had the learned intermediary [i.e., her doctor[5]] been warned adequately, the drug would not have been used, or would have been used differently." 5 Louis R. Frumer & Melvin I. Friedman, Products Liability § 50.05[4], at 50-84 (2010).

[5]It is well established that a manufacturer's duty to warn of a drug's safety risks "requires that the physician, not the patient, be warned." Brochu, 642 F.2d at 661. This is sometimes called the "learned intermediary" rule, because its underlying rationale "is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the [drug's] potential risks and benefits . . . and to advise the patient accordingly." Nelson, 1994 WL 255392, at *4 (quoting Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992)).

In moving for summary judgment on this issue, Bartlett argues that the deposition testimony of her treating physician, Dr. Ergin, proves that he would have prescribed a different drug with a lower risk of SJS/TEN if he had been given a stronger warning by Mutual of "what may well be [a] higher risk of severe reactions like SJS and TEN with Sulindac." Even if true, however, that addresses only the last link in the causal chain. The logically prior question, which Mutual raises in its own summary judgment motion, is whether a stronger warning by Mutual would have reached Dr. Ergin's attention in the first place, enabling it to affect his decision in that manner. As explained below, Bartlett has presented no evidence to establish that link in the causal chain. Indeed, the evidence in the record is to the contrary. Mutual is therefore entitled to summary judgment on this issue.

A. *Bartlett's doctor never reviewed the warning label*

At his deposition, Dr. Ergin made clear that he never reviewed Mutual's Sulindac label before treating Bartlett and that nothing about it influenced his decision to prescribe the drug or what he told her about it. Instead, he relied on his background knowledge of the drug's safety risks, including his knowledge that it could cause SJS/TEN. Thus, even assuming arguendo that Mutual had a duty to strengthen the SJS/TEN warning

on its Sulindac label, that stronger warning would not have affected Dr. Ergin's decision or prevented Bartlett's injuries. See, e.g., Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004) (affirming summary judgment based on lack of causation where plaintiff's "doctor testified that he did not read the warning label"); Porterfield v. Ethicon, Inc., 183 F.3d 464, 468 (5th Cir. 1999) (same); 5 Frumer & Friedman, supra, § 50.05[4], at 50-88 (noting that "most courts will find an absence of causation as a matter of law" where "the physician testifies that he or she never read the warnings given").

Bartlett argues that the jury could nevertheless find causation based on Dr. Ergin's review of the identical label for the brand-name drug, Clinoril. But Dr. Ergin testified at his deposition that he never reviewed the Clinoril label either ("no, not in detail" was his precise response). Even if one infers from that response that Dr. Ergin may have given the label a cursory review, he proceeded to acknowledge that he never read the part of the label that listed SJS/TEN as potential adverse reactions (in the "Adverse Reactions" section), nor the part that warned of "hypersensitivity" and "severe skin reactions" that have caused fatalities (in the "Warnings" section). Thus, even if those warnings had been stronger, as Bartlett alleges they should have been, they would not have reached Dr. Ergin's attention or prevented Bartlett's injuries.

Moreover, Bartlett has presented no evidence that if Mutual had strengthened its Sulindac label, the FDA would have required corresponding changes to the Clinoril label.[6] So far as the record indicates, that sequence of events (i.e., unilateral changes to a generic drug label, followed by FDA-mandated changes to the brand-name drug label) would have been highly unusual, if not unprecedented. Indeed, Bartlett herself points to this lack of precedent in arguing that it would be speculative for Mutual's experts to opine that the FDA would not have taken such action.[7] But she, too, has offered nothing but speculation. Since it is a

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[6]Even now, more than five years after Bartlett's prescription, the FDA has not mandated the sort of label changes that Dr. Ergin said would have influenced his prescription decision. In response to a citizen's petition filed by a group of doctors in 2005, the FDA required that all NSAID labels (including Sulindac's) use the following language in their "Warnings" section:

> NSAIDs, including [sulindac], can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Nothing in that warning suggests "what well may be [a] higher risk of severe reactions like SJS and TEN with Sulindac" (to use Dr. Ergin's phrase). If anything it implies that all NSAIDs have a similar risk of SJS/TEN. Thus, even if the label change is admissible (which the parties dispute, see Fed. R. Evid. 407), it hurts rather than helps Bartlett on the issue of causation.

[7]Document no. 151 at 6.

plaintiff's burden to prove causation, that evidentiary gap is fatal to any causation theory based on the Clinoril label. See Lockridge v. Univ. of Me. Sys., 597 F.3d 464, 471 n.6 (1st Cir. 2010) ("unsupported speculation . . . is insufficient to forestall summary judgment").

Bartlett attempts to fill the evidentiary gap by pointing to Mutual's legal position, which is that FDA regulations require a generic drug's label to remain the same as that of the brand-name drug. She seems to be arguing that Mutual is therefore estopped from contesting whether changes to the Sulindac label would have resulted in corresponding changes to the Clinoril label. But Mutual's position is that FDA regulations prohibit unilateral changes to generic drug labels, not that they require the brand-name drug label to copy such changes. In any event, Bartlett argued against Mutual's position in her objection to the earlier motion for judgment on the pleadings, and this court agreed with her. See Bartlett, 659 F. Supp. 2d at 304 (ruling that federal regulations "did not in fact require the generic drug's labeling to remain the same as [brand-name] drug's post-approval"). She cannot use her opponent's unsuccessful legal theory as a substitute for evidence of causation.

Bartlett also argues that she is not required to present evidence of causation because there is "a rebuttable presumption in favor of the plaintiff that a physician would have heeded an

adequate warning" if the drug's manufacturer had given one. Garside, 976 F.2d at 80 (citing Restatement (Second) Torts, § 402A, comment j). Whether that so-called "heeding presumption" applies under New Hampshire law is questionable. See Wilson v. Bradlees of New Eng., Inc., 250 F.3d 10, 16 (1st Cir. 2001) (declining to apply heeding presumption because the New Hampshire Supreme Court had not yet done so). But even assuming arguendo that it applies, the presumption has been rebutted by Dr. Ergin's deposition testimony, which makes clear that he did not review Mutual's Sulindac warning label before prescribing the drug to Bartlett and thus would not have heeded any changes that Mutual made to it.[8]

Finally, Bartlett argues that summary judgment is inappropriate because the jury could reject Dr. Ergin's testimony on credibility grounds. But that is always true of any witness's sworn statements submitted in support of summary judgment. A party's "bare assertion that the opposing party's uncontroverted

[8]Nor is Bartlett saved by the principle "that a physician's carelessness . . . should not relieve a drug manufacturer of liability if the manufacturer's failure to warn adequately may have contributed to that carelessness." Brochu, 642 F.2d at 660 (quoting McCue v. Norwich Pharmacal Co., 453 F.2d 1033, 1035 (1st Cir. 1972)). Nothing in the record suggests that Mutual's alleged failure to warn of SJS/TEN contributed to Dr. Ergin's decision not to read Sulindac's warning label or, for that matter, that he was careless in not doing so. As discussed above, Dr. Ergin already knew from his medical background that Sulindac could cause SJS/TEN.

evidence might be disbelieved is insufficient to resist judgment as a matter of law on an issue as to which the party resisting judgment bears the burden of proof." Favorito v. Pannell, 27 F.3d 716, 721 (1st Cir. 1994); see also Levesque v. Doocy, 560 F.3d 82, 87 (1st Cir. 2009) ("[A] mere challenge to the credibility of a movant's witness without any supporting evidence does not raise a trialworthy issue of fact.").

Bartlett points to "a line of cases holding that a physician's statement about what s/he would have done in the face of an adequate warning raises a credibility issue which must be decided by a jury," because that sort of "hindsight opinion is not conclusive." Garside, 976 F.2d at 83 n.9 (quoting Doe v. Miles Lab., Inc., 927 F.2d 187, 195 n.32 (4th Cir. 1991)). But Bartlett is the one who moved for summary judgment based on Dr. Ergin's opinion testimony about what he hypothetically would have done in response to a stronger warning. (She apparently sees credibility as no barrier to summary judgment in her favor on this issue.) Mutual, in contrast, moved for summary judgment based on Dr. Ergin's factual testimony about what he actually did before prescribing the drug. Such testimony is conclusive where, as here, it is not controverted by other evidence.

B. *Non-label theories*

At oral argument, this court also explored whether a stronger warning by Mutual could have reached Dr. Ergin's attention through some other means (apart from the label). Although Bartlett had not asserted any "non-label" theories of causation in her summary judgment objection, she seized the opportunity to do so when the court raised the theories at oral argument, arguing that she or Dr. Ergin would have seen the warning if Mutual had created a medication guide for Sulindac users, sent a "Dear Doctor" letter directly to healthcare providers, filed a citizen's petition with the FDA, or launched an educational campaign. Ordinarily, this court will not consider theories raised for the first time at oral argument, out of fairness to the adverse party. See, e.g., Johnson v. Gen. Dynamics Info. Tech., Inc., 675 F. Supp. 2d 236, 241 n.3 (D.N.H. 2009); Doe v. Friendfinder Network, Inc., 540 F. Supp. 2d 288, 309 n.19 (D.N.H. 2008).[9]

[9]Even after oral argument, both parties continued to present new theories on various summary judgment issues, inserting them (somewhat incongruously) into their briefs on the pending motions in limine. Bartlett, for example, argued that a stronger warning could have reached Dr. Ergin's attention through an FDA press release or health advisory. Since those arguments are untimely and improperly raised, this court will not consider them.

Even if considered on the merits, however, Bartlett's "non-label" theories would not prevent summary judgment on the issue of causation:

- Starting with the patient medication guide, it is well established that a manufacturer's duty to warn of a drug's safety risks "requires that the physician, not the patient, be warned." Brochu, 642 F.2d at 661; see also Nelson, 1994 WL 255392, at *4. Since Mutual had no duty to warn Bartlett directly, its failure to issue such a warning (in the form of a medication guide or otherwise) cannot serve as the basis for a finding of causation.

- Turning to the "Dear Doctor" letter, Bartlett admitted at oral argument that there is no evidence about whether Dr. Ergin has a practice of reading such letters. Moreover, there is little, if any, evidence about the process for distributing such letters. See, e.g., Demahy, 593 F.3d at 444-45 & n. 108 (suggesting that "generic manufacturers cannot send 'Dear Doctor' letters without prior FDA approval"). With the record in this undeveloped state, any causation theory based on a "Dear Doctor" letter is purely speculative.

- Bartlett also suggested at oral argument that Mutual should have filed a citizen's petition with the FDA requesting changes to the Sulindac and Clinoril labels, such as a "black box" warning of SJS/TEN. As she acknowledged, however, that theory puts her back in the same predicament discussed above, because Dr. Ergin never would have seen those label changes (even assuming arguendo that the FDA would have approved them).

- Finally, Bartlett suggested that Mutual should have launched an educational campaign to promote early monitoring of Sulindac's side effects. She emphasized at oral argument that the manufacturer of Bextra, another NSAID linked to SJS/TEN, advocated such a campaign to Canadian regulators. For purposes of causation, however, the key question is not whether Mutual should have advocated such a campaign, but what would have happened if it did. Because there is no evidence on that point, it is pure speculation to say that such a campaign would have prevented Bartlett's injuries.

All of these "non-label" theories, moreover, rest upon a dubious proposition: that even if Mutual had strengthened the SJS/TEN warning on its Sulindac label (i.e., disclosing prominently in the "Warnings" section that Sulindac had more

reported cases of SJS/TEN than any other NSAID and all but four other drugs, and listing all the potential complications of SJS/TEN), that still would have been a legally inadequate warning unless Mutual took additional steps beyond the label to disseminate such information. Bartlett has not identified any authority or evidence for that proposition. Indeed, as already discussed, it is debatable whether Mutual even had a duty to include such detailed information in the label itself. See Part III, supra.

In sum, Bartlett has not met her burden of coming forward with "specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue" as to whether Mutual's alleged failure to warn caused her injuries. Clifford v. Barnhart, 449 F.3d 276, 280 (1st Cir. 2006); see also Fed. R. Civ. P. 56(e)(2). Her causation theories "rest[] merely upon conclusory allegations, improbable inferences, and unsupported speculation." Meuser v. Fed. Express Corp., 564 F.3d 507, 515 (1st Cir. 2009). Mutual is accordingly entitled to summary judgment on Bartlett's claims of strict products liability (Count 1) and negligence (Count 6) based on failure to warn.

C. *Defective design claims*

After oral argument, this court ordered supplemental briefing to help determine whether this causation problem is

fatal to Bartlett's other claims of strict products liability (Count 2) and negligence (Count 6) based on defective design. Mutual argues those claims, too, are really failure-to-warn claims because the only "defect" that Bartlett alleges is an inadequate safety warning. But that is not accurate. Bartlett also alleges that Sulindac is defective because its safety risks outweigh its medical benefits, making it an unreasonably dangerous product.[10] As the New Hampshire Supreme Court has explained:

> A design defect exists when the product is manufactured in conformity with the intended design but the design itself poses unreasonable dangers to consumers. A strict liability action based upon a theory of defective design may be joined with an action grounded in negligence. To maintain a products liability claim based on defective design, a plaintiff must prove: (1) that the design of the product created a defective condition unreasonably dangerous to the user; (2) that the condition existed when the product was sold . . .; (3) that the use of the product was reasonably foreseeable by the manufacturer; and (4) that the condition caused injury to the user or the user's property.

Trull v. Volkswagen of Am., Inc., 145 N.H. 259, 264 (2000) (citations omitted). Such a claim is independent of any inadequacy in the product's safety warning and can be brought as an alternative ground for recovery under New Hampshire law. See

[10]Bartlett further alleges that Mutual should have removed Sulindac from the market in light of its unreasonable dangerousness. This court need not consider that issue here, though, because both parties agree that defective design claims do not require such a finding.

Brochu, 642 F.2d at 657 (explaining that it is "neither illogical nor inconsistent" to bring both claims in a case involving prescription drugs).

This is not to say, however, that Mutual cannot use Sulindac's safety warning as part of its defense against Bartlett's defective design claims. The New Hampshire Supreme Court has said that "[s]ome products are so important that a manufacturer may avoid liability [for defective design] as a matter of law if he has given proper warnings." Thibault, 118 N.H. at 808 (citing two cases that involved prescription drugs). This principle is explained more fully in the Restatement (Second) of Torts:

> **Unavoidably unsafe products.** There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies

> the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, cmt. k (1965); see also Bellotte v. Zayre Corp., 116 N.H. 52, 55 (1976) (citing cmt. k); Brochu, 642 F.2d at 656 (same).

Because this comment "is traditionally viewed as an exception and a defense to strict liability, courts generally place the initial burden of proving the various . . . factors on the defendant," meaning that "plaintiff's burden of proof on his or her prima facie case remains the same as in any products liability case." 1 Frumer & Friedman, supra, § 8.07[5], at 8-296; see also, e.g., Castrignano v. E.R. Squibb & Sons, Inc., 900 F.2d 455, 457 (1st Cir. 1990) (applying Rhode Island law). This court predicts that the New Hampshire Supreme Court would follow that majority approach, particularly since it has referred to the exception as a way "that a manufacturer may avoid liability," Thibault, 118 N.H. at 808, and has said that "proof of an alternative design" (i.e., avoidability) is not an essential element that must be proved by the plaintiff in a defective

design case. Vautour v. Body Masters Sports Indus., Inc., 147 N.H. 150, 156 (2001).

Applying these principles to the current record, this court concludes that Bartlett has presented enough evidence (primarily in the form of expert testimony) to create a trialworthy issue as to whether Sulindac is unreasonably dangerous and whether that defective condition caused her injuries. Assuming arguendo that the jury finds for her on those points, Mutual might nonetheless be able to avoid liability for defective design if it can prove, as an affirmative defense, that Sulindac is unavoidably unsafe and had an adequate safety warning. As explained above, however, the adequacy of Sulindac's safety warning is a matter of genuine dispute on this record. See Part III, supra. Because "a product without a proper warning, even if otherwise unavoidably unsafe, does not qualify for the strict liability exemption," 1 Frumer & Friedman, supra, § 8.07[5], at 8-276, summary judgment is inappropriate on Bartlett's defective design claims.

V. Fraud claim

Mutual also seeks summary judgment on Bartlett's fraud claim (Count 3). "To establish fraud" under New Hampshire law, "a plaintiff must prove that the defendant made a representation with knowledge of its falsity or with conscious indifference to its truth with the intention to cause another to rely upon it,"

and which actually induces justifiable reliance. Snierson v. Scruton, 145 N.H. 73, 77 (2000). This showing must be made by clear and convincing evidence. See, e.g., Burroughs v. Wynn, 117 N.H. 123, 124 (1977). On this record, Bartlett has not presented any evidence--much less clear and convincing evidence--of actual reliance on Mutual's allegedly fraudulent misrepresentations. To the contrary, the record shows that neither Bartlett nor her doctor read or relied upon Sulindac's warning label. See Part IV, supra. Summary judgment is therefore granted to Mutual on Bartlett's fraud claim.

VI. Enhanced compensatory damages

Mutual also seeks summary judgment on Bartlett's claim for enhanced compensatory damages. Under New Hampshire law, punitive damages are prohibited by statute, see N.H. Rev. Stat. § 507:16, but an award of compensatory damages may nevertheless be enhanced in "exceptional cases" where the defendant's tortious "act is wanton, malicious, or oppressive." Stewart v. Bader, 154 N.H. 75, 87 (2006). An act is "wanton" if the defendant recklessly creates a risk of great harm. See Minion, Inc. v. Burdin, 929 F. Supp. 521, 525 (D.N.H. 1996) (McAuliffe, D.J.) (citing Thompson v. Forest, 136 N.H. 215, 220 (1992)). An act is "malicious" if the defendant has "ill will, hatred, hostility, or evil motive."

Stewart, 154 N.H. at 87. An act is "oppressive" if it constitutes an abuse of power. See Walter L. Murphy & Daniel C. Pope, New Hampshire Civil Jury Instructions § 9.14, at 9-17 (1996). It is the plaintiff's burden "to present evidence of wanton, malicious or oppressive conduct." Figlioli v. R.J. Moreau Cos., 151 N.H. 618, 622 (2005).

Bartlett has presented enough evidence, particularly as to wantonness, to avoid summary judgment on this issue. The court cannot say, at least on the current record, that no reasonable jury could conclude that Mutual recklessly created a risk of great harm to consumers like Bartlett. For example, a finding of such recklessness could be based on Mutual's admitted (though explained) failure to survey the medical literature for information about Sulindac's safety risks and its continual manufacture and sale of Sulindac in the face of those risks, even though other drugs were withdrawn from the market based on a similar link to SJS/TEN. Mutual's request for summary judgment on this issue is therefore denied. The scope of Bartlett's claim for enhanced compensatory damages and this court's corresponding jury instruction will be determined based on the evidence at trial.

Mutual further argues that any award of enhanced compensatory damages must be based solely on its own conduct, not on the severity of Bartlett's injuries. It is true that

compensatory damages may be enhanced only if Mutual acted wantonly, maliciously, or oppressively (regardless of what injuries Bartlett suffered). But in analyzing Mutual's conduct, the jury may consider the nature of the risk that Mutual created. See Stewart, 154 N.H. at 87 (citing Aubert v. Aubert, 129 N.H. 422, 431 (1987), and Kowalski v. Gagne, 914 F.2d 299, 303 (1st Cir. 1990)). It is undisputed, for example, that Mutual knew Sulindac posed risks on the order of those Bartlett suffered. Moreover, Bartlett's actual injuries are a relevant factor in determining the amount of any enhancement. See id. at 88 (noting that the enhanced compensatory damage award in Aubert, 129 N.H. at 431, "was not excessive in light of the defendant's oppression and ill-will and the plaintiff's 'severe and traumatic' injuries").[11]

VII. Surveillance of medical literature

Next, Bartlett seeks summary judgment on the part of her negligence claim (Count 6) which alleges that Mutual breached its duty of care by failing to survey the medical literature for

[11]In its reply, Mutual also argues for the first time that an award of enhanced compensatory damages would violate its due process rights under the Fourteenth Amendment to the United States Constitution. This court generally "does not consider theories advanced for the first time in reply" and sees no reason to make an exception here. Friendfinder, 540 F. Supp. 2d at 303 (citing L.R. 7.1(e)(1), which restricts reply "to rebuttal of factual and legal arguments raised in the objection").

adverse events associated with Sulindac.[12] There is no factual dispute on this issue: Mutual concedes that it did not conduct such surveillance. But the parties disagree over the law. Bartlett argues that FDA regulations required generic manufacturers to survey the medical literature for adverse drug events and that those regulations establish the minimum standard of care under New Hampshire law. Mutual, in contrast, argues that FDA regulations imposed no surveillance requirement on generic manufacturers and, even if they did, only the federal government would have the power to enforce them.

This court already made clear in its earlier pre-emption ruling that 21 C.F.R. § 314.80(b), which requires brand-name drug manufacturers to "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA," applies equally to generic drug manufacturers by virtue of 21 C.F.R. § 314.98(a), which provides that they too "shall comply with the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences." See Bartlett, 659 F. Supp. 2d at 289, 307; accord Demahy, 593 F.3d at 448 ("The FDA also requires that generics

[12]Although this allegation played a more prominent role in Bartlett's failure-to-warn claims (and, to that extent, is moot), it is also relevant to her defective design claims, in that it bears on Mutual's degree of fault, if any, in selling an unreasonably dangerous product. See Part VI, supra.

'develop written procedures for the surveillance . . . of postmarketing adverse drug experiences to FDA.'") (quoting § 314.80(b)).

Mutual argues that § 314.98(a) makes generic manufacturers subject only to the specific subsections of § 314.80 entitled "Reporting requirements" and "Recordkeeping," see 21 C.F.R. §§ 314.80(c), (i), and not to the surveillance requirement in § 314.80(b), entitled "Review of adverse drug experiences." But the regulations make clear that "[a]ny person subject to the reporting requirements under paragraph (c)" of § 314.80 is also subject to the surveillance requirement. Id. § 314.80(b) (emphasis added). That language confirms this court's earlier conclusion that the surveillance requirement applies to generic manufacturers.

At oral argument, Mutual suggested that § 314.80(b) only requires manufacturers to develop procedures for collecting reports of specific adverse experiences associated with their own drugs, not for surveying the medical literature for broader safety studies (such as the international study of NSAIDs and SJS/TEN referenced in Part II, supra). But the regulation states that manufacturers "shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic," including specifically "reports in the scientific literature" and

"postmarketing epidemiological/surveillance studies." 21 C.F.R. § 314.80(b). The most logical interpretation is that those are the same types of sources that manufacturers must develop procedures for surveying.[13]

The question, then, is whether Mutual's admitted failure to develop safety surveillance procedures as required by federal law constitutes a per se violation of its duty of care under New Hampshire law. Unlike most states, New Hampshire generally regards "a causal violation of a statute [as] not merely evidence of fault but [as] legal fault," provided that the plaintiff is a member of the class protected by the statute and the harm is the type against which the statute is designed to protect. 8 Richard

[13]Mutual also argues that, under the doctrine of "primary jurisdiction," this court should defer to the FDA for a determination of which regulations apply to generic manufacturers and whether they have been violated. That doctrine "comes into play whenever enforcement of [a] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." United States v. W. Pac. R.R. Co., 352 U.S. 59, 64 (1956). But it was Mutual that initially asked this court to interpret the FDA regulations by moving for judgment on the pleadings based on its pre-emption defense, suggesting, at least, that it regarded the court as competent to resolve these issues. In any event, the interpretation of those regulations is not something for which the judiciary needs the FDA's special competence, as the growing and (so far) uniform body of case law interpreting and applying those regulations indicates. See, e.g., Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir. 2005) ("primary jurisdiction should seldom be invoked unless a factual question requires both expert consideration and uniformity of resolution") (quotation omitted).

B. McNamara, New Hampshire Practice, § 4.70, at 4-103 (citing cases). Both of those prerequisites seem to be satisfied here: the FDA's surveillance requirement is designed to protect patients like Bartlett against safety risks like SJS/TEN by ensuring that the drug's warning label reflects up-to-date information.

But the FDA's surveillance requirement is not a statute; it is a safety regulation. The New Hampshire Supreme Court has suggested that safety codes generally "are not to be accepted as absolute standards" of care "unless they have been incorporated into statutes or ordinances by either State or local legislative bodies." Lemery v. O'Shea Dennis, Inc., 112 N.H. 199, 200 (1972). That cautionary language casts serious doubt on whether New Hampshire would treat the violation of a safety regulation as negligence per se, particularly a federal regulation which, so far as the record indicates, has not been incorporated into any such statutes or ordinances. Cf. Mailhot v. C&R Constr. Co., 128 N.H. 323 (1986) (leaving this issue open in a case involving federal workplace safety regulations).

Another factor that New Hampshire courts consider in determining whether to recognize a negligence per se theory is whether doing so would be consistent with the legislative intent as expressed in the relevant law. See, e.g., Wong v. Ekberg, 148 N.H. 369, 375 (2002); Marquay v. Eno, 139 N.H. 708, 716 (1995).

Here, the FDCA expressly provides that "all such proceedings for [its] enforcement . . . shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has said that this provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001).

"Because the FDCA does not provide for a private cause of action, many courts have held plaintiffs cannot seek to enforce it through negligence per se tort actions." Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (citing Talley v. Danek Med., Inc., 179 F.3d 154, 161 (4th Cir. 1999) and other cases); see also Kemp v. Medtronic, Inc., 231 F.3d 216, 236 (6th Cir. 2000); Rimbert v. Eli Lilly and Co., 577 F. Supp. 2d 1174, 1239-40 (D.N.M. 2008).[14] Other courts, though, have allowed such suits, reasoning that they do not assert private rights of action under the FDCA, but rather a negligence theory long recognized at common law. See, e.g., In re Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 788-89 (3d Cir. 1999) (citing cases).

There is no clear answer to this question under New Hampshire law. In such cases, federal courts must make "an

[14]Indeed, Mutual even argues that doing so would raise federal pre-emption concerns, citing Buckman, 531 U.S. at 353.

informed prophecy of what the [state's highest court] would do in the same situation, seeking guidance in analogous state court decisions, persuasive adjudications by courts of sister states, learned treatises, and public policy considerations." Walton v. Nalco Chem. Co., 272 F.3d 13, 20 (1st Cir. 2001). Based on the sources and considerations discussed above, this court's view is that the New Hampshire Supreme Court would not treat Mutual's violation of 21 C.F.R. § 314.80(b) as establishing a per se breach of its duty of care, but rather would allow the jury to consider that violation as evidence of such a breach. See, e.g., Lemery, 112 N.H. at 201 (noting that "standards embodied in safety codes might be of aid to the trial court or the jury on an issue of due care"); 8 McNamara, supra, § 4.13, at 4-26 n.5.[15] Bartlett's request for summary judgment on this issue is therefore denied.

[15]In light of this ruling, the court need not decide whether premising a negligence per se claim on a violation of FDA regulations amounts to an impermissible private right of action under the FDCA. This court's ruling also avoids the pre-emption concerns raised by Mutual. See Buckman, 531 U.S. at 352-53 (allowing state-law claims to "parallel federal safety requirements" where they arise "from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements").

VIII. Mutual's affirmative defenses

Next, Bartlett seeks summary judgment on two of Mutual's affirmative defenses: (1) set-off and (2) spoliation.[16] Both defenses were originally stricken by this court in its discovery order following the preliminary pre-trial conference in October 2008, "without prejudice to being reinstated on request if warranted by the evidence."[17] Mutual, without making any evidentiary showing, reinstated both defenses in the answer to Bartlett's amended complaint that it filed in February 2010. Bartlett argues that neither Mutual's answer nor its summary judgment objection amounts to a formal request for reinstatement. But even construing them as such, this court sees no basis for reinstating either defense.

A. *Set-off*

[16]Bartlett initially challenged a large number of defenses, but Mutual conceded that some of them should be stricken (i.e., standing, unclean hands, laches, waiver, estoppel, statute of limitations, and excessive delay), and Bartlett withdrew some of her other challenges in her reply brief. She also withdrew one at oral argument (failure to mitigate). Another defense that she challenged (product modification) is moot in light of this court's ruling that Mutual is entitled to summary judgment on Bartlett's failure-to-warn claims, see Part IV, supra, since the defense was based on the pharmacy's decision to give Bartlett a pharmacy-created "prescription adviser" instead of Mutual's safety warning.

[17]Document no. 24.

According to Mutual, its "set-off" defense is based on its argument that fault should be apportioned to a third party, Dr. Ergin, or to Bartlett herself under New Hampshire's apportionment statute, N.H. Rev. Stat. § 507:7-e. But "set-off" is not the correct label for that defense. See, e.g., In re Liquidation of Home Ins. Co., 158 N.H. 677, 680 (2009) ("Setoff allows entities that owe each other money to apply their mutual debts against each other, thereby avoiding the absurdity of making A pay B when B owes A.") (quotation omitted). Moreover, Mutual has already asserted a specific apportionment defense, which Bartlett has not challenged, seeking reduction of its liability based on the conduct of third parties. In light of that defense, there is no need to reinstate Mutual's mislabeled set-off defense.

B. *Spoliation*

The spoliation defense is based on the fact that Mutual has never been allowed to inspect Bartlett's original Sulindac container and unused pills. But the transcript from Bartlett's deposition in May 2009 shows that the parties arranged for Mutual's counsel to contact Bartlett's counsel afterward to arrange such an inspection. That appears never to have happened. Bartlett recently sent Mutual pictures of the container and pills and confirmed her willingness to arrange an inspection in advance of trial. If Mutual still wishes to conduct the inspection, it

may do so by accepting one of the reasonable options offered by Bartlett's counsel.

Based on the pictures that Bartlett provided, Mutual also argues that the number of unused Sulindac pills (15 out of the original 60) is inconsistent with Bartlett's testimony about how many pills she took (40), thus indicating either that she took too many pills or that some pills were destroyed. But that discrepancy alone is not enough to warrant reinstatement of Mutual's spoliation defense, at least on the current record. Spoliation occurs where a party culpably destroys relevant evidence in her possession while under a duty to preserve it. See N.H. Ball Bearings, Inc. v. Jackson, 158 N.H. 421, 434 (2009). Mutual has not identified any evidence that Bartlett, who was in a coma for months after developing SJS/TEN, culpably destroyed pills while anticipating litigation.[18]

IX. Pre-emption redux

Finally, Mutual asks this court to revisit its earlier pre-emption ruling in light of the deposition testimony of three

[18]Of course, this is a pretrial ruling based on a summary judgment record. Nothing prevents Mutual from using the number of pills remaining to challenge Bartlett's testimony about the number of pills she took. If her testimony suggests culpable destruction, then Mutual may request that this court reconsider whether to give a spoliation instruction. See, e.g., Testa v. Wal-Mart Stores, Inc., 144 F.3d 173, 177 (1st Cir. 1998).

former FDA officials, each of whom testified that the FDA's policy is to prohibit manufacturers from unilaterally strengthening a generic drug's label. See Bartlett, 659 F. Supp. 2d at 279 (ruling that federal law allows such changes). But as Mutual concedes, those officials "were not deposed to offer opinions or interpretations of federal statutes or regulations." Their testimony thus has little, if any, relevance to the pre-emption issue and, indeed, plays a minimal role in Mutual's arguments in support of its motion. Cf. Rose v. Chase Bank USA, N.A., 513 F.3d 1032, 1038 n.4 (9th Cir. 2008) (noting that "no amount of discovery" would change the court's pre-emption ruling, which was based on congressional intent).

Although presented in the guise of a summary judgment motion, Mutual's argument is really one for reconsideration of the court's earlier ruling. See Rodriguez-Antuna v. Chase Manhattan Bank Corp., 871 F.2d 1, 2 (1st Cir. 1989) ("a motion which asks the court to modify its earlier disposition . . . solely because of an ostensibly erroneous legal result" is a motion for reconsideration). This court will therefore analyze it as such. A motion for reconsideration must "demonstrate that the order [being challenged] was based on a manifest error of fact or law" and must be filed within 14 days of the order, unless the party shows cause for not filing it within that time. L.R. 7.2(e). Here, Mutual filed its motion about six months

after this court's earlier ruling, long after the 14-day deadline.

Mutual seems to be suggesting that the depositions of former FDA officials constitute "newly available material evidence," which can be cause for a late filing under Local Rule 7.2(e). But as explained above, such evidence is not material or even relevant to the pre-emption issue. Nor is it truly "new." Mutual admitted at oral argument that at least two of the officials had testified many times in other cases and that it anticipated what they would say when deposed here. And even if the evidence were new and material, Mutual unreasonably delayed in filing its motion. One of the depositions took place less than a month after this court's earlier ruling, and even the most recent one occurred more than two months before Mutual's motion. This court therefore denies Mutual's motion for reconsideration as untimely.

Even if it were timely, Mutual's motion for reconsideration would still be denied because Mutual has not identified "a manifest error of fact or law" in this court's earlier ruling, which analyzed the relevant statutes and regulations in painstaking detail. Since that ruling, two federal circuit courts have reached the same conclusion that this court reached, based on substantially the same reasoning. See Demahy, 593 F.3d at 428; Mensing, 588 F.3d at 603. While generic drug

manufacturers (including Mutual) continue to refine and adapt their arguments in response to those unsuccessful outcomes, this court is not persuaded that those refinements change the fundamental analysis or the outcome.[19]

X. Conclusion

Mutual's motion for summary judgment[20] is GRANTED as to Bartlett's claims of strict products liability (Count 1) and negligence (Count 6) based on failure to warn, as well as her claim of fraud (Count 3), but is DENIED as to her claims of strict products liability (Count 2) and negligence (Count 6) based on defective design, as well as her request for enhanced compensatory damages. Mutual's separate motion for summary judgment based on federal pre-emption,[21] which is actually a motion for reconsideration of this court's earlier pre-emption ruling, is also DENIED. Bartlett's motion for partial summary judgment[22] is GRANTED as to Mutual's set-off and spoliation defenses, but is otherwise DENIED.

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[19]Since this court's pre-emption ruling remains in effect, Bartlett's competing request for summary judgment on issues relating to pre-emption is moot.

[20]Document no. 146.

[21]Document no. 145.

[22]Document no. 131.

SO ORDERED.

Joseph N. Laplante
United States District Judge

Dated: July 12, 2010

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